

I. Purpose

In accordance with section 10(a) of the Federal Advisory Committee Act, 5 U.S.C. App., this notice announces a meeting of the National Advisory Council for Healthcare Research and Quality (the Council). The Council is authorized by Section 941 of the Public Health Service Act, 42 U.S.C. 299c. In accordance with its statutory mandate, the Council is to advise the Secretary of the Department of Health and Human Services and the Director of AHRQ on matters related to AHRQ's conduct of its mission including providing guidance on (A) priorities for health care research, (B) the field of health care research including training needs and information dissemination on health care quality and (C) the role of the Agency in light of private sector activity and opportunities for public private partnerships. The Council is composed of members of the public, appointed by the Secretary, and Federal ex-officio members specified in the authorizing legislation.

II. Agenda

On Thursday, March 18, 2021, the Council meeting will convene at 10:00 a.m., with the call to order by the Council Chair and approval of previous Council summary notes. The meeting will begin with an update on AHRQ's recent accomplishments in Health Systems Research, Practice Improvement, Data and Analytics, and achieving organizational excellence. The agenda will also include a discussion of communication and value of health systems research, an update on PCOR Trust Funds, and a discussion of how AHRQ may advance health equity. The meeting will adjourn at 2:00 p.m. The meeting is open to the public. For information regarding how to access the meeting as well as other meeting details, including information on how to make a public comment, please go to <https://www.ahrq.gov/news/events/nac/>. The final agenda will be available on the AHRQ website no later than Thursday, March 11, 2021.

Dated: February 11, 2021.

Marquita Cullom,

Associate Director.

[FR Doc. 2021-03182 Filed 2-17-21; 8:45 am]

BILLING CODE 4160-90-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—Funding Opportunity Announcement (FOA), PAR 20-280, Cooperative Research Agreements to the World Trade Center Health Program (U01); and RFA OH-21-004, Exploratory/Developmental Grants Related to the World Trade Center Health Program (R21); Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—Funding Opportunity Announcement (FOA), PAR 20-280, Cooperative Research Agreements to the World Trade Center Health Program (U01); and RFA OH-21-004, Exploratory/Developmental Grants Related to the World Trade Center Health Program (R21), March 16-17, 2021, from 9:00 a.m.-6:00 p.m., EDT; and March 18, 2021, from 9:00 a.m.-12:00 p.m., EDT, in the original FRN.

The virtual meeting was published in the **Federal Register** on Monday, January 11, 2021, Volume 86, Number 6, pages 1975-1976.

The virtual meeting is being amended to change the dates and times and should read as follows:

Dates and Times: March 16-17, 2021, from 1:00 p.m.-5:00 p.m., EDT.

The meeting is closed to the public.

FOR FURTHER INFORMATION CONTACT:

Marilyn Ridenour B.S.N., M.B.A., M.P.H., C.P.H., C.I.C., CAPT, USPHS, Scientific Review Officer, CDC, National Institute for Occupational Safety and Health, 1095 Willowdale Road, Mailstop 1811, Morgantown, West Virginia 26505, Telephone (304) 285-5879.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021-03230 Filed 2-17-21; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; NIDA R13 Conference Grant Review.

Date: April 1, 2021.

Time: 11:00 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Preethy Nayar, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021 Bethesda, MD 20892, 301-443-4577 nayarp2@csr.nih.gov

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: February 11, 2021.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-03187 Filed 2-17-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Allogeneic Therapy for the Treatment of Autoimmune Disease Using Chimeric Antigen Receptors Targeting CD19

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this notice to Kyverna Therapeutics (“Kyverna”) located in Berkeley, CA.

DATES: Only written comments and/or complete applications for a license which are received by the National Cancer Institute’s Technology Transfer Center on or before March 5, 2021 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: David A Lambertson, Ph.D., Senior Technology Transfer Manager, NCI Technology Transfer Center at (240)-276-5530 or Email: david.lambertson@nih.gov.

SUPPLEMENTARY INFORMATION:**Intellectual Property**

The following represents the intellectual property to be licensed under the prospective agreement:

(A) U.S. Provisional Patent Application 62/006, 313 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-US-01], PCT Patent Application PCT/US2015/033473 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-PCT-02], Australian Patent 2015270912 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-AU-03], Canadian Patent Application 2951045 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-CA-04], Chinese Patent Application 201580033802.5 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-CN-05], European Patent 3149044 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-EP-06] (validated in Germany [HHS Ref. E-042-2014-0-DE-19], Spain [HHS Ref. E-042-2014-0-ES-20], France [HHS Ref. E-042-2014-0-FR-21], the United Kingdom [HHS Ref. E-042-2014-0-GB-22], Italy [HHS Ref. E-042-2014-0-IT-23], and Ireland [HHS Ref. E-042-2014-0-IE-24], and lodged in Hong Kong [E-042-2014-0-HK-16]), Israeli Patent Application 249305 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-IL-07], Indian Patent Application 291647041047

entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-IN-08], Japanese Patent Application 2016-571017 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-JP-09], South Korean Patent Application 2016-7036828 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-KR-10], Mexican Patent Application MX/a/2016/015834 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-MX-11], New Zealand Patent Application 727167 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-NZ-12], Saudi Arabian Patent Application 516380406 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-SA-13], Singaporean Patent Application 11201609960Q entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-SG-14], United States Patent 10,287,350 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-US-15], United States Patent Application 16/360,281 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-US-17], New Zealand Patent Application 764530 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-NZ-18], European Patent Application 20197459.9 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-EP-25], Australian Patent Application 2020267211 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-AU-26], and Japanese Patent Application XXX entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014-0-JP-27], and all continuing U.S. and foreign patents/patent applications for the technology family.

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the following:

“The development, production and commercialization of an anti-CD19 targeting chimeric antigen receptor (CAR)-based immunotherapy using CRISPR/Cas9-edited allogeneic (where donor and recipient are different) T lymphocytes, wherein the CAR expresses at least:

- (1) The complementary determining region (CDR) sequences of the anti-CD19 antibody known as Hu19;
- (2) a CD8a hinge and transmembrane domain*;

(3) and a CD28z T cell signaling domain*;

for the treatment of autoimmune diseases.”

This technology discloses the development of chimeric antigen receptors that recognize the CD19 cell surface protein. CD19 is expressed on the cell surface of several autoimmune disease cells, including lupus nephritis. For many autoimmune diseases there are no FDA-approved therapies, underscoring that there is an unmet need. The development of an autoimmune disease therapeutic targeting CD19 will benefit public health by providing a treatment for patients who may not have any options.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a completed license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: February 4, 2021.

Richard U. Rodriguez,
Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2021-03221 Filed 2-17-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of General Medical Sciences Special Emphasis Panel, March 23, 2021, 09:30 a.m. to March 23, 2021, 05:30 p.m., National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD, 20892 which was published in the